FACTS YOU NEED TO KNOW ABOUT LASER ASSISTED IN-SITU KERATOMILEUSIS (LASIK) SURGERY FOR THE REDUCTION OR ELIMINATION OF LOW-TO-MODERATE NATURALLY OCCURRING HYPEROPIA UP TO +4.00 DIOPTERS MRSE, WITH SPHERE BETWEEN +1.00 TO +4.00 DIOPTERS WITH OR WITHOUT REFRACTIVE ASTIGMATISM OF UP TO+2.00 DIOPTERS AT THE SPECTACLE PLANE WHEN USED AS PART OF THE LASIK PROCEDURE WITH THE BAUSCH & LOMB TECHNOLAS® 217A EXCIMER LASER SYSTEM

PATIENT INFORMATION BOOKLET

Please read this entire booklet. Discuss its content with your doctor so that all your questions are answered to your satisfaction. Ask any questions you may have before you agree to the surgery.

Bausch & Lomb, Incorporated
180 E. Via Verde Drive
San Dimas, California 91773

Refractive Hotline:
(800) 496-7457

Bausch & Lomb and Technolas are trademarks of Bausch & Lomb Incorporated and/or its affiliates. Other products/brands are trademarks of their respective owners.

TABLE OF CONTENTS

TABLE OF CONTENTS
(cont.)

PAGE

INTRODUCTION

This booklet contains information to help you decide whether or not to have Laser Assisted In-Situ Keratomileusis (LASIK) laser surgery for the correction of farsightedness. You should understand that there are alternative methods of correcting farsightedness. These other methods include: glasses, contact lenses, photorefractive keratectomy (PRK), incisional refractive keratotomy (RK) lamellar refractive keratotomy, or other types of refractive surgery. LASIK, using the Bausch & Lomb excimer laser system, is a completely different type of surgery than RK, but somewhat similar to PRK.

If you are farsighted in both eyes, it may be necessary to have both eyes treated with LASIK. Sometimes, it is better to have LASIK done on only one eye. Talk with your doctor about whether it would be better to treat one eye or both eyes.

Please read this booklet completely and discuss your questions with your doctor. Only your eye care professional can determine whether or not you are a suitable candidate. Some jobs, such as military pilots, have vision requirements that RK, PRK, and LASIK presently cannot meet.

HOW THE EYE FUNCTIONS

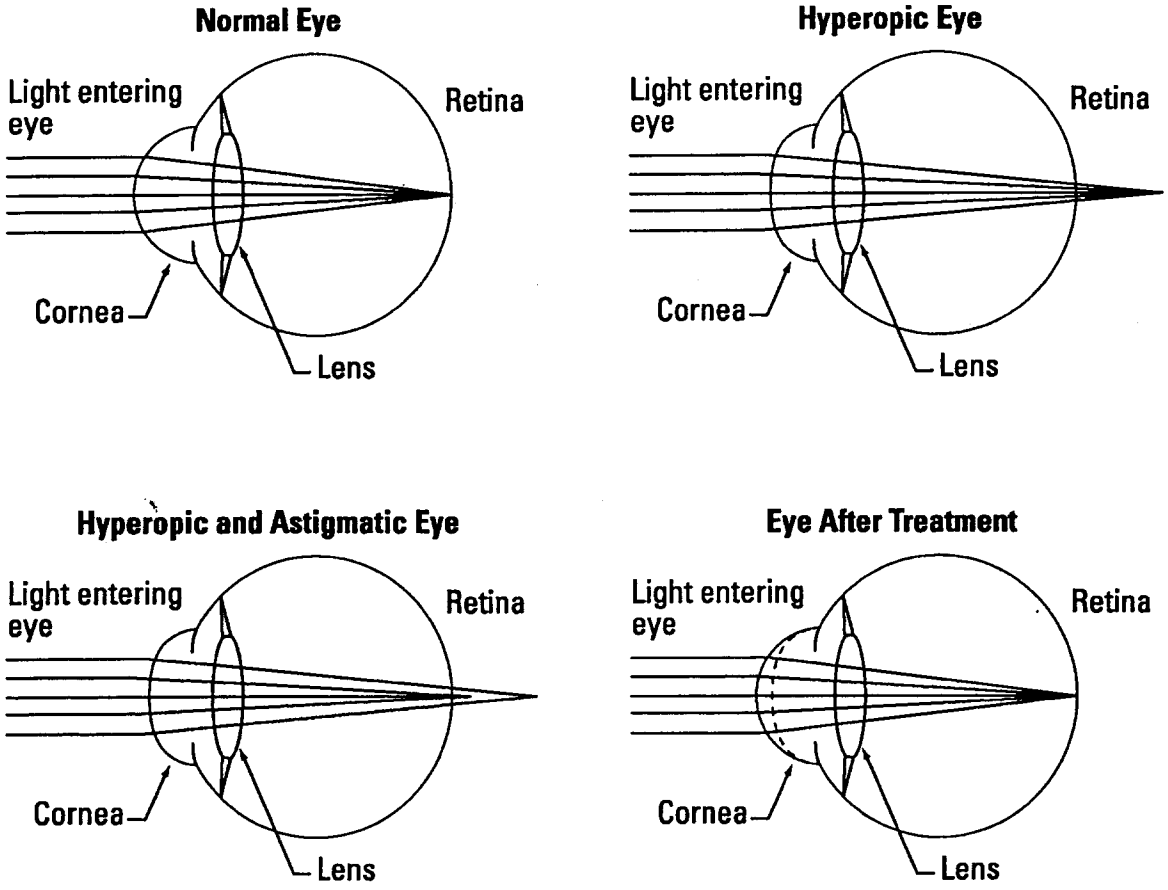
Your eye focuses light to form images or "pictures" much like a camera. Your eye changes the images into electrical signals and sends them to the brain. If your eye is out of focus, what you see is blurred.

The cornea at the front of the eye bends the light toward your retina. The clear tissue of the cornea is responsible for two-thirds of the focusing power of the eye. The lens within the eye finishes the job of focusing the light onto your retina.

Focusing with Your Eye

The eye focuses light by bending all light rays to meet at a single point. If it works perfectly, a sharp image of the object you look at will be focused exactly on the retina. You will see a clear image. However, if the light focuses either in front of or behind the retina, the image you see will be blurred. Depending on where the image focuses, you will be nearsighted, farsighted, or astigmatic.

The shape of the cornea determines the focusing power of the eye. The more sharply curved the cornea, the more that light rays are bent. If the cornea is too flat, the image focuses behind the retina and the eye is farsighted. If the cornea is curved too much, the image focuses in front of the retina and the eye is nearsighted. If the cornea is irregularly shaped (like a football rather than a basketball), it is called astigmatic.



Checking Your Focus

Your doctor checks where your eye focuses light. When your vision is corrected, a lens or a combination of lenses is added to move the point where the light focuses so that the focal point strikes your retina perfectly. Good focus depends on the shape and size of your eyeball, the shape of your cornea, and the power of your natural lens.

The Farsighted Eye

Farsighted people see near objects less clearly than distant objects, the degree to which both near and distant objects are blurred depends on the level of farsightedness. Light rays focus behind the retina instead of directly on it. Farsightedness can be corrected by glasses, contact lenses or refractive surgery.

Glasses and contact lenses can be adjusted if vision changes over time. Changes due to refractive surgery are usually permanent and cannot be undone if vision or focus changes. If your vision

changes or the initial surgery is not completely successful, additional treatments may be performed to try to improve your results.

WHAT IS LASER ASSISTED IN-SITU KERATOMILEUSIS (LASIK)?

LASIK is a surgical treatment for farsightedness. A small surgical instrument called a microkeratome, which is much like a carpenter's plane, is used to make a very thin flap of tissue on the cornea (the clear part on the front of the eye). This flap is then folded out of the way, and an excimer laser is used to reshape the front surface of the cornea below the flap. The laser removes small amounts of tissue with ultraviolet light. After the laser treatment is finished, the corneal flap is placed back into its original position on the cornea. This is different from RK. In RK, a surgical knife is used to make deep cuts around the center of the cornea.

An excimer laser is a machine that produces and aims a powerful beam of ultraviolet light. The excimer laser produces a brief, intense pulse that lasts only a few billionths of a second. Each pulse removes a microscopic amount of tissue from the surface of the cornea. It produces little heat and leaves the tissue beneath unchanged.

LASIK surgery is performed on one eye at a time. The second eye can be treated if all goes well with the first eye. Laser surgery on the second eye can usually be done on the same day as the first eye, or may be done later, depending on your doctor's evaluation of your particular case.

Benefits

LASIK surgery, performed with the Bausch & Lomb TECHNOLAS® 217A Excimer Laser System reduces low-to-moderate hyperopia of +1.00 to +4.00 diopters with or without astigmatism up to +2.00 diopters with no more than 4.0 diopters of Manifest Refractive Spherical Equivalent when used as part of the LASIK surgical procedure.

LASIK may reduce overall farsightedness while reducing or eliminating dependency on contact lenses or glasses.

LASIK surgery, performed with the Bausch & Lomb TECHNOLAS® 217A Excimer Laser System, is a reasonably safe and effective alternate way to correct farsightedness.

Risks

LASIK surgery may not completely correct your distance vision. If you are farsighted but have no astigmatism, you are likely to remain somewhat farsighted after treatment, and to have some astigmatism induced (caused) by the treatment. The amount of induced astigmatism is usually less than one diopter but can possibly be more than two diopters. The more farsighted you are before treatment, the more remaining farsightedness and induced astigmatism you can expect.

If you have farsightedness and astigmatism, LASIK treatment may overcorrect your astigmatism, leaving you with some astigmatism at a different axis (angle). The amount of astigmatism remaining can be more than you had before surgery, and can be more than two diopters. In some cases, large changes in the astigmatism axis can make your vision distorted and uncomfortable.

In addition, it is possible that LASIK surgery may make your best corrected vision with glasses or contact lenses worse than it was before surgery. In addition, you may require glasses or contact lenses for some activities after LASIK treatment.

LASIK surgery may cause visual problems or symptoms that you did not have before the surgery, or may make such pre-existing problems or symptoms worse following the surgery.

There is a risk of infection of the cornea or other parts of the eye, as a result of the LASIK surgery, due to removal of tissue from the front surface of the eye as part of the procedure.

There is a risk of perforation (cutting completely through the cornea) of the eye during the microkeratome portion of the surgery to create the corneal flap, which could lead to loss of fluid from inside the eye, cataract formation, and infection of the eye.

During the First Week Following Surgery

- Pain and discomfort may last for up to 7 days after surgery.
- Blurred vision and tearing will occur as the cornea heals.
- You may be sensitive to bright lights.

For the First Week to One Month Following Surgery

- The pressure in your eye may increase due to use of anti-inflammatory medications. When you stop the medication or use other drug therapy, the pressure elevation usually resolves.
- Your cornea may become hazy or cloudy enough to affect your vision. This haze disappears over time. Some patients continue to experience haze up to 6 months after the surgery.

3 Months or Longer After Surgery

Some patients report visual complaints. These are discussed in the clinical results section on page11.

Contraindications

You should **NOT** have LASIK surgery if:

- You have collagen, vascular, autoimmune, or immunodeficiency disease (e.g., lupus or AIDS).
- You are pregnant or nursing.
- You show signs of keratoconus (a corneal disease) or have any other condition that causes thinning of your cornea.
- You are taking Accutane (isotretinoin) for acne treatment or Cordarone (amiodarone hydrochloride) for controlling normal heart rhythm.

Warnings

Discuss with your doctor if:

- You have a systemic disease likely to affect wound healing, such as connective tissue disease, diabetes, severe atopic disease or an immunocompromised status.
- You have had *Herpes simplex* or *Herpes* zoster infections.
- Your farsightedness is changing

Precautions

The safety and effectiveness of the Bausch & Lomb TECHNOLAS® 217A Excimer Laser System have **NOT** been established:

- In patients with unstable or worsening farsightedness or astigmatism.
- In patients with diseased or abnormal corneas (scars, infections, etc.).
- In patients with previous surgery or injury to the center of the cornea where LASIK will be performed.

- In patients with abnormal blood vessels within 1.0 mm of the center of the eye where LASIK will be performed.
- In patients under 21 years of age.
- In patients taking hormone replacement therapy or antihistamines.
- In patients taking sumatripin (Imitrex) for migraine headaches.
- In patients with a history of glaucoma.
- In patients with refractive treatments >4.00 D of farsightedness or >+2.00D of astigmatism.
- In patients with corneas too thin for the procedure to be completed.
- In patients with a tendency to form scars.
- For LASIK retreatments
- In patients who have had prior refractive surgery
- Over the long term (after 1 year)

The effects of LASIK on visual performance under poor lighting conditions have not been determined. It is possible, following LASIK treatment, that patients will find it more difficult than usual to see in conditions such as very dim light, rain, snow, fog, or glare from bright lights at night. Visual performance possibly could be worsened by large pupil sizes.

Before surgery, your doctor should evaluate your pupil size under dim lighting conditions. If your pupils in dim light are greater than the optical zone proposed by your doctor (which ranges from 5.0mm to 6.0mm), consult with your doctor about the risk that the surgery may cause negative effects on your vision, such as glare, halos, and night driving difficulty.

Your doctor should also evaluate you for dry eyes before surgery. LASIK surgery may worsen symptoms associated with dry eyes and, in addition, you may have dry eyes after LASIK surgery even if you did not have dry eyes before surgery.

ARE YOU A GOOD CANDIDATE FOR LASIK?

If you are considering LASIK, you must:

- Be 21 years of age or older.
- Have healthy eyes free from retinal problems, corneal scars, and any eye disease.
- Have farsightedness within the range of treatment: +1.00 to +4.00 diopters sphere with up to +2.00 diopters of astigmatism with no more than 4.0 diopters of Manifest Refractive Spherical Equivalent.
- Have written proof that the change in your vision is one-half diopter or less per year for at least one year before your pre-surgery exam.
- Be fully informed about the risks and benefits of LASIK as compared to other treatments for farsightedness.
- Be able to lie flat without difficulty.

- Be able to keep your eye accurately on the red fixation light during the entire LASIK procedure.
- Be willing to sign an Informed Consent Form provided by your eye care professional.
- Be able to tolerate eye drops to numb your eye.

WHAT YOU NEED TO KNOW ABOUT THE SURGERY

Before the Surgery

If you are interested in LASIK, you will need a pre-surgical examination to determine if your eye is healthy and suitable for LASIK. The exam includes a physical and eye history. Both eyes will be checked. Your cornea will be mapped by computer to determine if it is smooth and properly shaped.

WARNING: If you wear contact lenses, the doctor will ask you to stop wearing them two to four weeks before your exam. Failure to do this may produce poor surgical results.

Before surgery, talk to your doctor about any medicine you take. Also discuss whether or not you should eat and drink just before surgery. You should arrange to have someone drive you home after surgery and to your next doctor's appointment. You should not drive until your doctor gives you permission.

The Day of Surgery

Before the actual surgery, you will be given the opportunity to hear the sounds the laser makes so that you will be prepared for the noise during surgery. You will be given some numbing drops in the eye that will be treated. When you go into the room that contains the laser system, you will see a large machine that has a computer screen, a surgeon's chair and a patient bed. You will be asked to lie down on the bed. You will lay face up toward the laser's microscope and the ceiling. Your eye may be numbed with more drops. The eye not having surgery may be covered with a temporary shield.

The surgery takes about 10-20 minutes overall. The use of the laser, however, lasts only about 30 to 60 seconds. The doctor will place a small spring-like device between your eyelids to hold them open.

When the surgery begins, the surgeon will place a suction ring on your eye, which will raise the pressure inside of the eye, and vision will go black as pressure increases. The microkeratome will then cut a thin flap of corneal tissue that is folded away from the cornea after the suction is released. The doctor will then reposition your head under the microscope. You will be asked to look directly at the red light. Even though the eye not having the surgery may be covered by a drape or a patch, try to keep both eyes open without squinting. This makes it easier to keep

looking at the red light. You will then hear the noise the laser makes when it is delivering the laser energy. Small amounts of tissue will be removed from the cornea by the laser.

WARNING: It is very important that you keep looking directly at the red light, even if the light fades or dims, to prevent the treatment from being off-center. Your results depend on how well you look directly at this red light throughout the treatment.

Immediately After the Surgery

After the surgery, your doctor will put some medicated drops or ointment into your eye. Your doctor may apply a patch or protective shield to your eye for protection and comfort.

Numbing drops make the surgery painless. When these drops wear off, your eye may hurt for a day or two. Most patients describe the pain as moderate to severe. Your doctor may prescribe pain medicine to make you more comfortable. Do not remove the patch or shield until instructed to do so. Do not rub or touch your treated eye for the first one to seven days after surgery.

First Days After Surgery

The patch or shield is usually removed the next day. You may be mildly sensitive to light and glare. Wearing sunglasses may make you more comfortable. You may also have the feeling that something is in your eye. This happens while the outer layer of your cornea is healing.

Your vision should begin to stabilize within a few weeks. Some patients report small changes in vision such as improvement or worsening. These changes may occur up to six months or more after surgery.

You may see a haze or cloudiness in the cornea following surgery. It usually does not affect your vision. This haze tends to decrease over time. It usually disappears completely by 12 to 24 months after the surgery but some patients continue to experience haze.

Use any prescribed drops and lubricants as directed by your doctor. Your surgical results depend on carefully following your doctor's directions. If topical steroids are used, the doctor should monitor you for potential side effects of long term use, including ocular hypertension, glaucoma, or cataract formation.

RESULTS FROM THE CLINICAL STUDY

In the clinical study of the Bausch & Lomb TECHNOLAS® 217A Excimer Laser System, 61.4% of all treated eyes had far vision of 20/20 or better without glasses after a single LASIK procedure, and 94.8% had far vision of 20/40 or better at the 6 month visit. Although vision without glasses improved for all eyes, some patients still needed glasses or contact lenses after LASIK. All eyes (100%) at month six had far vision of 20/40 or better with glasses or contact

lenses (best corrected distance vision). Of the eyes that had far vision of 20/20 or better before LASIK, 98.9% had far vision of 20/25 or better with glasses or contact lenses after LASIK. LASIK to correct distance vision does not eliminate the need for reading glasses. It is possible that you may need reading glasses after laser surgery even if you did NOT wear them before.

The clinical study showed the following consistent errors in correcting distance vision:

- LASIK surgery did not fully correct farsightedness in most eyes. The amount of remaining farsightedness was 0.31 diopter on average, and more than one diopter for 12% of the treated eyes.
- Astigmatism treatments tended to be too strong, leaving most patients with some astigmatism at a very different axis than before the treatment. Of eyes with axis shifts greater than 30°, 16% had at least 1 diopter of astigmatism 6 months after surgery and 3% had at least 2 diopters. Such overcorrections of astigmatism can cause visual distortions that are disturbing to the patient.
- Of all eyes treated for astigmatism, 18% had more astigmatism 6 months after surgery than they had before surgery.
- The treatment created astigmatism in most farsighted patients who had no astigmatism before. The amount of induced astigmatism tended to be larger in patients who were more farsighted before surgery.

The Bausch and Lomb clinical studies showed that for the following problems more than 1% of patients reported that these problems were worse at 6 months or longer after the surgery, than before the surgery:

Patient Symptom	3 Months		6 Months		9 Months		≥ 12 Months	
	Worse (%)	Significantly Worse (%)	Worse (%)	Significantly Worse (%)	Worse (%)	Significantly Worse (%)	Worse (%)	Significantly Worse (%)
Light Sensitivity	19.8	10.0	18.6	7.2	15.5	6.0	12.0	3.6
Headaches	6.1	1.5	4.2	0.8	2.5	0.5	4.2	1.2
Pain	6.7	0.9	4.9	0.8	3.5	0.5	0.6	1.8
Redness	15.0	3.4	11.4	4.5	11.6	2.5	17.5	1.8
Dryness	28.7	14.6	32.7	11.3	30.5	10.5	7.2	1.2
Excessive Tearing	3.0	0.0	4.5	1.1	3.0	2.0	4.8	0.6
Burning	10.4	3.7	12.1	1.5	11.2	2.0	10.8	1.2
Gritty Feeling	14.9	4.3	15.5	5.3	12.7	1.5	12.0	2.4
Glare	23.2	5.5	24.2	4.5	21.7	1.5	18.6	1.2
Halos	16.6	5.8	13.6	7.5	12.6	4.5	10.8	3.0
Blurry Vision	21.0	9.6	20.2	10.3	22.2	5.1	20.5	6.0
Double Vision	9.8	4.9	9.8	4.9	9.1	3.0	11.4	1.8
Ghost Images	14.4	3.4	14.0	4.2	10.6	2.0	10.8	0.6
Fluctuation of Vision	36.3	11.3	32.5	9.8	31.8	8.6	29.9	6.6
Variations of Vision in Bright Light	19.6	10.7	17.4	6.1	15.2	5.1	13.2	5.4
Variations of Vision in Normal Light	23.5	5.2	20.8	5.7	19.7	5.6	19.2	4.8
Variations of Vision in Dim Light	24.6	10.2	22.3	14.3	21.3	12.7	20.4	11.4
Difficulties with Night Driving	14.4	4.0	12.1	6.4	17.2	2.5	16.2	1.2

* Number of CRFs received with non-missing values at both the preoperative visit and the indicated follow-up visit.

1.1% reported Other - Eye Strain at 6 months

1.3% reported Other - Allergies at ≥ 12 months

Fourteen eyes of nine patients (3.1% of all patients) reported using spectacles or contact lenses for distance vision tasks at the 6-month visit. Three of the patients received a monovision correction and therefore the use of spectacles for certain distance tasks is not unexpected. Details of spectacle and contact lens use are in the following table.

Wearing Spectacles and Contact Lenses for Distance Vision

Spherical Hyperopia Treatments	1 Month n/N (%)	3 Months n/N (%)	6 Months n/N (%)	9 Months n/N (%)	≥ 12 Months n/N (%)
Overall	3/164 (1.8%)	5/186 (2.7%)	9/157 (5.7%)	0/110 (0.0%)	3/121 (2.5%)
For driving	0/163 (0.0%)	0/185 (0.0%)	2/156 (1.3%)	0/110 (0.0%)	2/120 (1.7%)
For night driving only	0/163 (0.0%)	1/185 (0.5%)	3/156 (1.9%)	0/110 (0.0%)	0/120 (0.0%)
For watching TV or movies	0/163 (0.0%)	0/185 (0.0%)	0/156 (0.0%)	0/110 (0.0%)	2/120 (1.7%)
For sporting events	0/163 (0.0%)	1/185 (0.5%)	1/156 (0.6%)	0/110 (0.0%)	1/120 (0.8%)
For all distance	2/163 (1.2%)	2/185 (1.1%)	4/156 (2.6%)	0/110 (0.0%)	1/120 (0.8%)
For blurry vision	0/163 (0.0%)	1/185 (0.5%)	0/156 (0.0%)	0/110 (0.0%)	0/120 (0.0%)
Not reported*	6	4	5	0	0
Total†	170	190	162	110	121
Hyperopic Astigmatism Treatments	**1 Month n/N (%)**	**3 Months n/N (%)**	**6 Months n/N (%)**	**9 Months n/N (%)**	**≥ 12 Months n/N (%)**
Overall	6/135 (4.4%)	2/146 (1.4%)	5/111 (4.5%)	5/99 (5.1%)	5/44 (11.4%)
For driving	2/134 (1.5%)	1/146 (0.7%)	0/111 (0.0%)	2/99 (2.0%)	2/44 (4.5%)
For night driving only	0/134 (0.0%)	1/146 (0.7%)	0/111 (0.0%)	0/99 (0.0%)	2/44 (4.5%)
For watching TV or movies	0/134 (0.0%)	1/146 (0.7%)	2/111 (1.8%)	2/99 (2.0%)	4/44 (9.1%)
For sporting events	0/134 (0.0%)	1/146 (0.7%)	1/111 (0.9%)	1/99 (1.0%)	1/44 (2.3%)
For all distance	2/134 (1.5%)	1/146 (0.7%)	2/111 (1.8%)	4/99 (4.0%)	2/44 (4.5%)
For blurry vision	1/134 (0.7%)	0/146 (0.0%)	0/111 (0.0%)	0/99 (0.0%)	0/44 (0.0%)
Not reported	4	1	1	0	0
Total	139	147	112	99	44

Each patient could have multiple reasons for wearing spectacles or contact lenses.

At month 6, 2.8% of eyes lost at least two lines of vision on the eye chart, with glasses or contact lenses, compared to their pre-LASIK vision. During the Bausch and Lomb clinical trials, **doctors** reported the following complications:

Key Safety, Adverse Events, & Complications	3 Months n/N (%)	6 Months n/N (%)	≥12 Months n/N (%)	Cumulative* n/N (%)
Key Safety Events				
Loss of ≥ 2 lines on the vision chart with glasses	16/341 (4.7%)	8/290 (2.8%)	8/172 (4.7%)	18/358 (5.0%)
Far vision worse than 20/25 with glasses if 20/20 or better preoperatively	8/319 (2.5%)	3/268 (1.1%)	4/168 (2.4%)	7/333 (2.1%)
Increased astigmatism of > 2.0 D	2/196 (1.0%)	1/178 (0.6%)	0/130 (0.0%)	3/211 (1.4%)
Refractive astigmatism treatment error > 2.0 D	1/147 (0.7%)	2/112 (1.8%)	0/44 (0.0%)	2/147 (1.4%)
Loss of > 2 lines on the vision chart with glasses	5/341 (1.5%)	2/290 (0.7%)	0/172 (0.0%)	3/358 (0.8%)
Far vision worse than 20/40 vision with glasses	2/341 (0.6%)	0/290 (0.0%)	0/177 (0.0%)	1/358 (0.3%)
All Adverse Events Reported in >1% of Eyes				
Lamellar keratitis (inflammation of the corneal flap)	0/343 (0.0%)	0/290 (0.0%)	0/178 (0.0%)	6/358 (1.7%)
Anterior membrane dystrophy (patches of loose or irregular corneal tissue)	4/343 (1.2%)	3/290 (1.0%)	1/178 (0.6%)	4/358 (1.1%)
All Complications Reported in > 1% of Eyes				
Debris in interface (material underneath the flap)	18/343 (5.2%)	9/290 (3.1%)	8/178 (4.5%)	54/358 (15.1%)
Corneal edema (swelling) at/before 1 month	0/343 (0.0%)	0/290 (0.0%)	0/178 (0.0%)	24/358 (6.7%)
Opacity, crystalline lens (cataract)	0/343 (0.0%)	5/290 (1.7%)	5/178 (2.8%)	10/358 (2.8%)
Conjunctivitis (inflammation of the membrane lining the eyelid and the white of the eye)	2/343 (0.6%)	4/290 (1.4%)	4/178 (2.2%)	8/358 (2.2%)
Peripheral corneal epithelial defect (on the flap)	0/343 (0.0%)	1/290 (0.3%)	0/178 (0.0%)	8/358 (2.2%)
Epithelial defect (a piece of the outer cornea that has torn off)	1/343 (0.3%)	0/290 (0.0%)	0/178 (0.0%)	8/358 (2.2%)
Blepharitis (inflammation of the eyelids)	2/343 (0.6%)	4/290 (1.4%)	3/178 (1.7%)	7/358 (2.0%)
Epithelium in the interface with loss ≤ 2 lines of BSCVA (Best Spherical Corrected Visual Acuity)	1/343 (0.3%)	4/290 (1.4%)	0/178 (0.0%)	5/358 (1.4%)
Epithelial ingrowth (anterior corneal cells growing underneath the flap)	3/343 (0.9%)	2/290 (0.7%)	1/178 (0.6%)	5/358 (1.4%)
Guttata (abnormal cells on the back of the cornea)	0/343 (0.0%)	1/290 (0.3%)	0/178 (0.0%)	5/358 (1.4%)
Papillae (bumps on the inner eyelid)	2/343 (0.6%)	0/290 (0.0%)	0/178 (0.0%)	4/358 (1.1%)

The following adverse events and complications occurred during the clinical study at rates of less than 1%:
Edema (swelling) of the flap, Aborted (not finished) procedure, Blurry Vision, Red eye, Double Vision, Ghost Images, Keratitis (inflammation of the cornea), Pain, Pterygium (growth of conjunctiva onto the cornea), Trichiasis (eyelash growth toward eye), Folds in the flap, Allergies, Wrinkles in the back of the cornea, Corneal abrasion, Corneal Erosion (defect in the outer layer), Itching, Meibomitis (inflammation of the eyelid glands), Partial (incomplete) flap, Sub-Conjunctival Hemorrhage (broken blood vessel over the white of the eye)

The following adverse events and complications observed during the clinical study are not believed to be related to the LASIK procedure:
Heart Attack, Mini-Stroke, Bell's Palsy (facial paralysis), Retinal membrane growth, Punctal (tear drainage canal) blockage, Angioplasty, Surgery other than excimer laser, Chalazion (eyelid lump), Vitreal (gel inside eye) problems, Sebaceous cyst (eyelid bump)

QUESTIONS TO ASK YOUR DOCTOR

- What are the other options for correcting farsightedness?
- Will I have to limit my activities after the treatment? If yes, for how long?
- What are the benefits of LASIK for my level of farsightedness?
- What vision can I expect in the first few months after surgery?

- If LASIK does not correct my vision, could my vision be worse than before? Could my need for glasses increase over time?
- Will I be able to wear contact lenses if I still need them after LASIK?
- How is LASIK likely to affect my need to use glasses or contact lenses as I get older?
- Will my cornea heal differently if I injure it after having LASIK?
- Should I have LASIK surgery in my other eye?
- How long will I have to wait before I can have LASIK surgery on my other eye?
- What vision problems will I experience if I have LASIK only in one eye?

Discuss the cost of surgery and follow-up care with your doctor. Most health insurance policies do not cover excimer laser treatment for vision correction.

SUMMARY OF IMPORTANT INFORMATION

- LASIK is permanent. Once performed, it is not reversible.
- LASIK to correct distance vision does **NOT** eliminate the need for reading glasses, even if you have never worn them.
- Your vision must be stable for at least one year before LASIK surgery. You will need written proof that your farsightedness has not changed by more than 0.50 diopters.
- Pregnant and nursing women should wait to have the surgery.
- You would not be a good candidate if you have any medical condition that makes wound healing difficult.
- The LASIK treatment may cause you discomfort.
- The surgery is not risk-free. Please read this entire booklet, especially the sections on Benefits and Risks, before you agree to the treatment.
- LASIK is not a laser version of radial keratotomy (RK). These operations are completely different from each other.
- Some alternatives to LASIK include glasses, contact lenses, photorefractive keratectomy (PRK), and RK.
- Some jobs, such as military pilots, have vision requirements that RK, PRK, or LASIK do not presently meet.

Before considering LASIK you should:

Have a complete eye examination.

Talk with one or more eye care professionals about the potential benefits of LASIK and the complications, risks and time required for healing.

GLOSSARY OF TERMS

astigmatism: Refractive error which prevents light rays from coming to a single point of focus on the retina because of different degrees of bending of light by the various meridians of the eye.

cornea: Transparent front portion of the eye that covers the iris, pupil, and anterior chamber, and provides most of an eye's optical focusing power.

diopter: Unit of measurement of optical strength or refractive power of lenses.

excimer laser: A medical device that produces a very powerful and pure beam of light of a single specific wavelength (color) that is used to remove tissue from the clear front part of the eye (cornea). This is done in a computer-controlled fashion to re-shape the cornea to correct refractive errors. This re-shaping allows incoming light rays to be more accurately focused on the retina.

farsightedness/ hyperopia: Condition in which the eye is "under-powered,"so that parallel light rays from a distant object strike the retina before coming to a sharp focus; true focal point is said to be "behind the retina." Corrected with additional optical power, supplied by a "plus" lens or by additional use of the eye's own focusing ability.

halos: Hazy ring around bright lights seen by some patients with refractive error or optical defects (e.g., cataracts or corneal swelling).

keratoconus: Hereditary, degenerative corneal disease characterized by generalized thinning and cone-shaped protrusion of the central cornea.

LASIK: An acronym for "laser assisted in-situ keratomileusis." This is a surgical procedure in which a very thin flap of tissue on the clear front part of the eye (cornea) is made using a small surgical instrument called a microkeratome, which is much like a carpenter's plane. The flap is then folded out of the way and an excimer laser is used to flatten the front surface of the cornea below the flap.

lens: A transparent, colorless body located in the front third of the eyeball, between the aqueous and the vitreous, the function of which is to help bring rays of light to focus on the retina.

nearsightedness/ myopia:	"Overpowered" eye in which parallel light rays from a distant object are brought to focus in front of the retina. Requires "minus" lens correction to "weaken" the eye optically and permit clear distance vision.
pupil:	The opening at the center of the iris of the eye for the transmission of light, which varies in diameter depending upon the brightness of the light coming into the eye.
PRK:	An acronym for "photorefractive keratectomy." This is a surgical procedure in which a thin portion of the clear front part of the eye (cornea) is removed by the excimer laser in a predetermined manner to re-shape the cornea to correct refractive errors of the eye.
refractive surgery:	Several different procedures used for altering the shape of the cornea and thus how it bends light, in order to change or correct the eye's refractive error.
retina:	The thin lining of the back of the eye that converts images from the eye's optical system into electrical impulses sent to the brain.
RK:	An acronym for "radial keratotomy." This is a surgical procedure in which a predetermined number of radial cuts are made in the periphery of the cornea. This allows the central cornea to change shape and thereby reduces refractive error.

PATIENT ASSISTANCE INFORMATION

PRIMARY EYE CARE PROFESSIONAL

Name:
Address:

Telephone Number:

LASIK DOCTOR

Name:
Address:

Telephone Number:

LOCATION WHERE TREATMENT WAS DONE

Name:
Address:

Telephone Number:

LASER MANUFACTURER

TECHNOLAS GmbH Ophtalmologisch Systeme
Hans-Riedl-Str.7-9
D-85622 Feldkirchen
Germany

(011) 498994004-421

SALES AND SERVICE

Bausch & Lomb, Incorporated
180 E. Via Verde Drive
San Dimas, California 91773
United States of America

Refractive Hotline:
(800) 496-7457

INDEX

J

K

L

M

N

P

R

S

T

V

W